510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K201494

B Applicant

Advin Biotech, Inc.

C Proprietary and Established Names

ATTEST Drug Screen Cup ATTEST Drug Screen Dip Card

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
DJG	Class II	21 CFR 862.3650 - Opiate Test System	TX - Clinical Toxicology
DKZ	Class II	21 CFR 862.3100 - Amphetamine test system	TX - Clinical Toxicology
DIO	Class II	21 CFR 862.3250 - Cocaine and cocaine metabolite test system	TX - Clinical Toxicology
LCM	Unclassified		
NGG	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology
JXM	Class II	21 CFR 862.3170 - Benzodiazepine test system	TX - Clinical Toxicology
DIS	Class II	21 CFR 862.3150 - Barbiturate test system	TX - Clinical Toxicology
LDJ	Class II	21 CFR 862.3870 - Cannabinoid test system	TX - Clinical Toxicology
JXN	Class II	21 CFR 862.3700 - Propoxyphene test system	TX - Clinical Toxicology
DJR	Class II	21 CFR 862.3620 - Methadone test system	TX - Clinical Toxicology

Product Code(s)	Classification	Regulation Section	Panel
LFG	Class II	21 CFR 862.3910 - Tricyclic antidepressant drugs test system	TX - Clinical Toxicology
DJC	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:
Addition of new cutoff of 20ng/mL for THC-COOH (Marijuana 20) to a previously cleared device (K182123).

B Measurand:
6-Acetylmorphine, d-Amphetamine, Benzoylecgonine, Buprenorphine, EDDP, d/l-Methadone, d-Methamphetamine, d/l-Methylenedioxymethamphetamine, Morphine, Nortriptyline, Oxazepam, Oxycodone, Phencyclidine, d-Propoxyphene, Secobarbital and THC-COOH

C Type of Test:
Qualitative lateral-flow immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):
The ATTEST Drug Screen Cup and ATTEST Drug Screen Dip Card are rapid lateral flow immunoassays for the qualitative detection of 6-Acetylmorphine, d-Amphetamine, Benzoylecgonine, Buprenorphine, EDDP, d/l-Methadone, d-Methamphetamine, d/l-Methylenedioxymethamphetamine, Morphine, Nortriptyline, Oxazepam, Oxycodone, Phencyclidine, d-Propoxyphene, Secobarbital and THC-COOH in human urine. The test cutoff concentrations and the compounds the tests are calibrated to are as follows:

Assay	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
6-Acetylmorphine	6AM	6-monoacetylmorphine	10
Amphetamine	AMP	d-Amphetamine	500
Amphetamine	AMP	d-Amphetamine	1,000
Secobarbital	BAR	Secobarbital	300
Oxazepam	BZO	Oxazepam	300
Buprenorphine	BUP	Buprenorphine	10

Assay	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
EDDP	EDDP	2-ethylidene-1,5-dimethyl-3-3diphenylpyrrolidine	300
Cocaine	COC	Benzoylecgonine	150
Cocaine	COC	Benzoylecgonine	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methamphetamine	MET	d-Methamphetamine	500
Methamphetamine	MET	d-Methamphetamine	1,000
Marijuana	THC	11-nor-Δ^9-THC-9-COOH	20
Marijuana	THC	11-nor-Δ^9-THC-9-COOH	50
Methadone	MTD	d/l-Methadone	300
Opiates	OPI	Morphine	300
Opiates	OPI	Morphine	2,000
Oxycodone	OXY	Oxycodone	100
Phencyclidine	PCP	Phencyclidine	25
Propoxyphene	PPX	Propoxyphene	300
Nortriptyline	TCA	Nortriptyline	1,000

The single or multi-test panels can consist of the above listed analytes in any combination, up to a maximum of 16 analytes, with and without on-board adulteration/specimen validity tests (SVT) in the dip card format or in the cup format. Only one cutoff concentration per analyte will be included per device. The drug screen tests are intended for prescription use only.
The tests provide only a preliminary result. A more specific alternative chemical method should be used in order to obtain a confirmed presumptive positive result if the donor doesn't admit use or anytime required by testing procedures. Gas Chromatography / Mass Spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry (LC/MS) and their tandem mass-spectrometer versions are the preferred confirmatory methods. Careful consideration and judgment should be applied to any drugs of abuse screen test result, particularly when evaluating preliminary positive results.

B Indication(s) for Use:
Refer to intended use.

C Special Conditions for Use Statement(s):
Rx - For Prescription Use Only
For in vitro diagnostic use only.

D Special Instrument Requirements:
Not applicable.

IV Device/System Characteristics:

A Device Description:
The ATTEST Drug Screen Cup and ATTEST Drug Screen Dip Card devices are immunochromatographic assays that use a lateral flow system for the qualitative detection of 6-Acetylmorphine, d-Amphetamine, Benzoylecgonine, Buprenorphine, EDDP, d/l-Methadone, d-Methamphetamine, d/l-Methylenedioxymethamphetamine, Morphine, Nortriptyline, Oxazepam, Oxycodone, Phencyclidine, d-Propoxyphene, Secobarbital and THC-COOH. There are two available test formats: integrated cup and dip card. Both formats utilize the same test strip. The ATTEST Drug Screen Cup device consists of a cup device and a package insert. The ATTEST Drug Screen Dip Card device consists of a Dip Card device, a package insert and a urine cup for sample collection.

B Principle of Operation:
The Advin Biotech ATTEST Drug Screen Cup and Dip Card are rapid lateral flow immunoassays, based on the principle of competitive binding, between a chemically labeled drug (drug-protein conjugate) and the drug or drug metabolites which may be present in the urine sample competing for the limited antibody binding sites. If target drugs are present in the urine specimen below the cut-off concentration of the assay, the solution of the colored antibody-colloidal gold conjugate that has been rehydrated by the urine sample migrates by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test (T) region. The colored antibody-gold conjugate then binds with the drug-protein conjugate to form visible lines in the test (T) regions. If the level of drug in the urine specimen is below the cutoff, the T line appears and if they are above the cutoff, no T line develops. A separate antibody-antigen reaction serves as an internal quality control as control line (C) line which must appear on the strip to interpret the results regardless of the presence of the drug.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Advin Multi-Drug Screen Test Cassette, Dip Card And Cup

B Predicate 510(k) Number(s):
K122809

C Comparison with Predicate(s):

Device & Predicate Device(s):	K201494	K122809
Device Trade Name	Advin Biotech ATTEST Drug Screen Cup and Dip Card	Advin Multi-Drug Screen Test Cassette, Dip Card And Cup
General Device Characteristic Similarities		
Intended Use/Indications for Use	Same	Qualitative detection of drugs of abuse and/or their metabolites in human urine
Methodology	Same	Lateral flow immunochromatographic assay based on competitive binding
Specimen	Same	Human urine
Test formats	Same	Cup and Dip Card
Intended use	Same	For Prescription Use Only
General Device Characteristic Differences		
Analytes cutoffs (ng/mL)	Same except for the following analyte: Marijuana- 20	Amphetamine - 500 Amphetamine - 1,000 Barbiturates - 300 Benzodiazepine - 300 Buprenorphine - 10 Cocaine - 150 Cocaine - 300 EDDP - 300 Ecstasy - 500 Methamphetamine - 500 Methamphetamine - 1,000 Methadone - 300 Morphine - 300 Opiates - 2,000 Oxycodone - 100 Phencyclidine - 25 Propoxyphene - 300 Tricyclics - 1,000 Marijuana – 50

VI Standards/Guidance Documents Referenced:

Not applicable.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

Analytical performance for 15 analytes, besides Marijuana-THC-COOH detected with a 20 ng/mL cutoff (6-Acetylmorphine, d-Amphetamine, Benzoylecgonine, Buprenorphine, EDDP, d/l-Methadone, d-Methamphetamine, d/lMethylenedioxymethamphetamine, Morphine, Nortriptyline, Oxazepam, Oxycodone, Phencyclidine, d-Propoxyphene, Secobarbital, and Marjiuana-THC-COOH at 50 ng/mL) were conducted on k122809 and k182123. The analytical performance of the device for the measurement of these analytes continues to be supported by data provided in k122809 and k182123.

1. Precision/Reproducibility:
   The sponsor conducted a precision study for 11-nor-Δ9 -THC-COOH at three external sites. Eight participants tested nine (9) solutions containing ±100%, ±75%, ±50%, ±25% and cutoff levels of 11-nor-Δ9 -THC-COOH in twenty (20) replicates for each device format at each site.

   Samples were prepared with drug free urine spiked with certified 11-nor-Δ9 -THC-COOH reference standards to the target concentrations. The samples contained following drug concentrations: negative, -75% cutoff, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff, +75% cutoff and +100% cutoff.

Precision Study Result of ATTEST Drug Screen Cup

Drug Test	Results	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
THC 20	Neg	60	60	60	49	34	3	0	0	0
	Pos	0	0	0	11	26	57	60	60	60
	Total	60	60	60	60	60	60	60	60	60
	Agreement	100.00%	100.00%	100.00%	81.67%	-----	95.00%	100.00%	100.00%	100.00%

Precision Study Result of ATTEST Drug Screen Dip Card

Drug Test	Results	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	+25% Cutoff	+50% Cutoff	+75% Cutoff	+100% Cutoff
THC 20	Neg	60	60	60	51	35	5	0	0	0
	Pos	0	0	0	9	25	55	60	60	60
	Total	60	60	60	60	60	60	60	60	60
	Agreement	100.00%	100.00%	100.00%	85.00%	---	91.67%	100.00%	100.00%	100.00%

2. Linearity:
   Not applicable. Devices intended for qualitative determinations only.

3. Analytical Specificity/Interference:

Cross-reactivity: Analytical specificity for both the ATTEST Drug Screen Cup and the ATTEST Drug Screen Dip Card for each assay was determined by testing drug free urine samples spiked with certified standards of chemically-related or structurally-similar compounds. The relative cross-reactivity (if any) represents the minimum concentration necessary to yield a result similar to the cutoff level of the respective assay.

Performance data for Amphetamine (500 ng/mL cutoff), Barbiturates, Benzodiazepines, Buprenorphine, EDDP, Cocaine (150 ng/mL cutoff), Ecstasy, Methamphetamine (500 ng/mL cutoff), Marijuana, Methadone, Opiates (2000 ng/mL cutoff), Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants was provided in k122809.

Performance data for 6-Acetylmorphine devices (10 ng/mL cutoff, 6-AM 10), Amphetamine (1000 ng/mL cutoff, AMP 1000), Barbiturates, Benzodiazepines, Methadone (300 ng/mL cutoff), Cocaine (300 ng/mL cutoff, COC 300), EDDP (300 ng/mL cutoff), Methamphetamine (1000 ng/mL cutoff, MET 1000), Opiates (300 ng/mL cutoff, OPI 300), and Marijuana (50ng/mL cutoff, THC-50) was provided in k182123.

Assay/Cutoff	**Compound**	**Concentration (ng/mL)**	**Relative cross reactivity (%)**
THC 20	11-nor-Δ^9-THC-COOH	20	100
	(±)-11-Hydroxy-Δ^9-THC	10,000	0.2
	Δ^8-THC	>100,000	<0.02
	Δ^9-THC	25,000	0.08
	Cannabinol	>100,000	<0.02
	Cannabidiol (CBD)	>100,000	<0.02

Interference: The potential interference (whether positive or negative) from compounds chemically dissimilar to target drugs, known endogenous agents, urine pH and specific gravity variances was also determined. Testing of compounds and endogenous agents was performed by spiking the substances into pooled urine containing target drugs at near-cutoff concentrations. Unless otherwise indicated, substances were tested for potential interference at concentrations of 100 µg/mL.

The following substances demonstrated no positive or negative interference on the assays encompassed in this submission when tested in samples bearing target drugs at +/-50% of stated cutoff.

Acetaminophen	Acetone	Acetylsalicylic acid (aspirin)
Albumin	Ampicillin	Ascorbic acid
Aspartame	Atropine	Benzocaine

Bilirubin	Caffeine	Chloroquine
Chlorpheniramine	Creatine	Dexbrompheniramine
Dextromethorphan	Dimethylaminoantipyrine	Diphenhydramine
Dimenhydrinate	Dopamine	Isoproterenol
(+)-Ephedrine	Erythromycin	Ethanol
Furosemide	Gabapentin	Glucose
Guaiacol glyceryl ether	Hemoglobin	Ibuprofen
Ketamine	Lidocaine	Methylephedrine
Naproxen	Niacinamide	Nicotine
Norephedrine	Oxalic acid	Pantoprazole
Penicillin-G	Pheniramine	Phenothiazine
l-Phenylephrine	B-Phenylethylamine	Pregabalin
Procaine	Quinidine	Ranitidine
Riboflavin	Sertraline	Sodium chloride
Sulindac	Theophylline	Tyramine

To evaluate the potential effect of variances in urine pH on the assays, pooled urine specimens containing target drugs at near-cutoff concentrations were pH adjusted from 4.0 to 9.0 in increments of 1.0 and tested in duplicate.

To evaluate the potential effect of variances of urine specific gravity on the assays, pooled urine specimens containing target drugs at near-cutoff concentrations were diluted using deionized water or concentrated using sodium chloride to achieve specific gravity results of 1.003, 1.010, 1.015, 1.020, 1.025 and 1.030. Each solution was tested in duplicate.

The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.003 to 1.030 do not affect the results of the THC-20 assay.

Performance data for Amphetamine (500 ng/mL cutoff), Barbiturates, Benzodiazepines, Buprenorphine, EDDP, Cocaine (150 ng/mL cutoff), Ecstasy, Methamphetamine (500 ng/mL cutoff), Marijuana, Methadone, Opiates (2000 ng/mL cutoff), Oxycodone, Phencyclidine, Propoxyphene, and Tricyclic Antidepressants was provided in k122809.

Performance data for 6-Acetylmorphine devices (10 ng/mL cutoff, 6-AM 10), Amphetamine (1000 ng/mL cutoff, AMP 1000), Barbiturates, Benzodiazepines, Methadone (300 ng/mL cutoff), Cocaine (300 ng/mL cutoff, COC 300), EDDP (300 ng/mL cutoff), Methamphetamine (1000 ng/mL cutoff, MET 1000), Opiates (300 ng/mL cutoff, OPI 300), and Marijuana (50ng/mL cutoff, THC-50) was provided in k182123.

4. Assay Reportable Range:
   Not applicable.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

The Advin Biotech ATTEST Drug Screen Cup and Dip Card are traceable to a commercially available standard.

This device has internal process controls. A control (C) lines (lines from a separate antibody-antigen reaction forms appearing in the control region) confirms sufficient sample volume and proper test technique. The lack of a visible control (C) line indicates an insufficient specimen volume or improper test technique and the test must be repeated. There are no external controls supplied with the device.

Device stability has been evaluated through accelerated and real-time studies. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims that the devices are stable for 28 months.

6. Detection Limit:
Not applicable.

7. Assay Cut-Off:
For characterization of how the device performs analytically around the claimed cutoff concentration, please refer to section VII.A.1 and VII. B.1.

B Comparison Studies:

1. Method Comparison with Predicate Device:
The sponsor performed a method comparison study of the ATTEST Drug Screen Cup and Dip card using clinical urine specimens previously quantitated for THC-COOH by chemically specific quantitative methods (e.g., LC/MS). Identical results, provided in the table below, were obtained with the two devices. The results are shown in the table below. Method comparison studies demonstrating device accuracy when measuring previously cleared analytes can be found in K122809 and K182123.

Drug Test/Cutoff (ng/mL)	Result	Drug free	Drug quantitation by chemically specific method relative to assay cutoff level					
			-50% C/O to <-25% C/O	-25% C/O to C/O	C/O to +25% C/O	>+25% C/O to +50% C/O	>+50% C/O	Agreement
THC/20	Neg	40	22	6	2	0	0	98.55%
	Pos	0	0	1	1	5	46	96.30%

Summary of Discordant Results, ATTEST Cup format

Drug Test/ Cutoff (ng/ml)	ATTEST Cup Result	Result w/ GC/MS or LC/MS	
		Drug Concentration (ng/ml)	Analyte
THC/20	Positive	17.4	11-nor-Δ9-THC-9-COOH
	Negative	21.11	11-nor-Δ9-THC-9-COOH
	Negative	22.55	11-nor-Δ9-THC-9-COOH

2. Matrix Comparison:
   Not applicable. This assay is intended to be used with urine samples only.

C Clinical Studies:

1. Clinical Sensitivity:
   Not applicable.

2. Clinical Specificity:
   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

D Clinical Cut-Off:
Not applicable.

E Expected Values/Reference Range:
Not applicable.

VIII Proposed Labeling:

The proposed labeling is deemed sufficient based on the outcomes of all intended user studies and meets the requirements of 21 CFR 809.10.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.